This record is a partial extract of the original cable. The full text of the original cable is not available.

UNCLAS SECTION 01 OF 02 PRAGUE 000147

SIPDIS

STATE FOR EUR/NCE AND EB/TPP/MTA/IPC
COMMERCE FOR 4232/ITA/MAC/MROGERS
STATE PASS USTR FOR LERRION

E.O. 12958: N/A
TAGS: ETRD KIPR EZ USTR
SUBJECT: CZECH GOVERNMENT TAKES NOTICE OF WARNINGS ON PHARMACEUTICAL MARKET ACCESS

REF: PRAGUE 76

¶1. Summary: U.S. pharmaceutical companies' concerns about obstacles to market access in the Czech Republic will be raised in their 2005 Special 301 submission. Embassy Prague has raised with the GOCR the pharma industry's complaints about the discriminatory effect of Ministry of Health setting of reimbursement levels for the national health insurance and Ministry of Finance setting of maximum prices, as well as other practices that tend to restrict market access. The pharmaceutical industry's complaints are now beginning to get attention from the GOCR. The Ministry of Health is preparing new rules for determining reimbursement with the input of the pharma companies, although it remains to be seen if the result will be helpful or not. The right to appeal the Ministry of Health's reimbursement decrees remains unclear. Our contact at the Ministry of Health has promised to review specific claims of discrimination. Similarly, the Ministry of Foreign Affairs has promised to study the impact of the Ministry of Finance maximum price decrees. End Summary.

¶2. The Embassy has followed up the Ambassador's letter and meeting with the Ministry of Trade and Industry reported reftel with meetings with the Ministry of Health and Ministry of Foreign Affairs. The intent of these meetings is to use the leverage provided by the Special 301 process to ensure that the relevant Czech officials take notice of the U.S. pharmaceutical industry's concerns and begin to take action to address them.

HEALTH MINISTRY WORKING ON NEW REIMBURSEMENT SYSTEM

¶3. On January 24, we met with Katarina Bartikova, head of the Pharmacy Department of the Ministry of Health. As such, she is the official in charge of the process of setting reimbursement levels for the national health insurance system. Bartikova has been in her job since December, although she worked for the Pharmacy Department prior to a hiatus during which, she said, she was working for an American pharmaceutical company that she refused to name. Bartikova said she is determined to bring more transparency to the reimbursement process. She is preparing a new process for determining reimbursement levels with what she terms clear standards. Bartikova has met five or six times since December with MAFS (the International Association of Pharmaceutical Companies, the local association of U.S. and European pharma companies) to discuss what the standards should be. (Note: based on her prior work at the Ministry, local representatives of U.S. pharmaceutical companies view Bartikova as an adversary. They are skeptical of her commitment to setting fair standards.)

¶4. The new standards for reimbursement mentioned by Bartikova are apparently still a work in progress. The paper she showed us is relatively clear about the information that must be gathered by the Ministry, but it remains rather vague about the rules that will be applied to that information to reach a decision on a level of reimbursement.

¶5. Regarding the actual setting of reimbursement levels, we agreed that there will always be tension between the Ministry's desire to keep costs as low as possible and the pharma industry's desire that its products be reimbursed to the full extent possible. Bartikova agreed as well that the industry should have an opportunity to argue that a particular patented product has such special properties that it belongs in a different therapeutic category than the generic, with a correspondingly different reimbursement, even if it treats the same disease. One of the problems the U.S. industry has had heretofore has been getting a fair chance to make that argument.

¶5. With respect to claims that the system of reimbursement discriminates in favor of domestic products in the same therapeutic category as imported products, Bartikova said that each such case depends on the facts and asked us to provide particulars. With the pharma companies' permission, we have shared with her the detailed statement of their concerns that will likely form the basis of their Special 301 submission.

¶6. Although the pharma industry has long been critical of the "categorization committee" that advised the Minister of Health on reimbursement decisions, it was dismayed when Minister Emmerova's dismissed it last year because of its inattention to "social democratic values" in its work. Bartikova did not seem convinced of a need for such a committee in the first place and was not in a hurry to reconstitute it. She said that the new standards should be in place before appointing a new committee can be considered. She also linked the companies' right to appeal the Minister's final reimbursement decree to the establishment of standards. She was unwilling to say whether or not she believed such decisions are appealable.

MINISTRY OF FOREIGN AFFAIRS DEFENDS THE STATUS QUO

¶7. On January 27, we met with Jana Reinisova, Director of the Domestic Markets and Sectorial Policies unit of the European Union Department of the Ministry of Foreign Affairs. Reinisova gave us a paper (cleared with other interested ministries) responding to concerns raised by USTR in a recent telephone conversation with the Czech Embassy in Washington. For the most part, the paper contains flat denials of the allegations as they were understood by the MFA from the Czech Embassy. It also contains figures on the growth of public expenditure for drugs and on the growth of Czech expenditures for medicines produced by the U.S. company Eli Lilly. According to the Ministry, these expenditures have grown from Kc 556.6 million ($24.2 million) in 2001 to Kc 787.1 million ($34.2 million) in 2003, with expenditures for the first half of 2004 already at Kc 475.8 million ($20.6 million).

¶8. We discussed with Reinisova the current top concern of the pharmaceutical industry, which is a new decree of the Ministry of Finance that, according to a legal analysis commissioned by MAFS, subjects domestically-produced drugs to a simpler calculation of maximum price than imported drugs. The producer of imports must submit information on direct costs of material, direct salaries, other direct costs, indirect costs and profit. The pharma companies contend that this formulation is disadvantageous to them. Reinisova was not familiar with the new decree but promised to study it.

SPECIAL 301 WILL PUT THE PROBLEM IN FOCUS

¶9. Comment: The Czech government has historically been sensitive to the possibility that it may be placed on the Special 301 watch list. The Ambassador's letter (reftel) and the USTR inquiry to the Czech Embassy have already put the working levels of the Ministries of Health, Foreign Affairs and Trade and Industry on their mettle to defend the Czech system as it affects imported products. A strong response from the GOCR to Phrma's formal Special 301 submission can be expected. The industry's complaints seem to be influencing the Ministry of Health to attempt to create at least a veneer of transparency for the reimbursement process. The involvement of MAFS in determining the standards is encouraging, but it remains to be seen whether the ultimate result will allow the pharmaceutical companies to get a handle on how reimbursement prices are actually set and create a basis for a reasoned appeal if necessary. End Comment.

CABANISS